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WASHINGTON OFFICE

December 20, 1999

Ms. Paula McKeever
Docket Number 97N-484S
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Ms. McKeever:

Thank you for providing the opportunity to comment on the proposed regulation regarding the suitability determination for donors of human cellular and tissue-based products.

The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty society organized for educational and scientific purposes, Its 75,000 members include board certified pathologists, other physicians, clinical scientists (PhD), and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the world's leading organization for the certification of laboratory personnel. ASCP's certifying board registers more than 150,000 laboratory professionals annually.

ASCP believes that additional donor suitability requirements will improve safety and protect public health by reducing the risk of transmission of communicable diseases. ASCP supports the intent of the proposed regulation and believes that guidance from the Food and Drug Administration (FDA) is needed in the area of human cell and tissue donation. However, ASCP requests clarification regarding the following sections of the regulation.

Section 1271.80(d)(l)(i) allows donations to be made by a donor whose specimen has tested repeatedly reactive for cytomegalovirus (CMV). The test to be used for CMV is listed in the regulation as an "FDA-cleared test for anti-CMV." Since the term "repeatedly reactive" is not recognized as a CMV screening test result, we suggest using the term "repeatedly positive" as an indication of the result.

Section 1271.85 states that a donor specimen of viable or nonviable cells or tissue shall be tested-for human immunodeficiency virus, Hepatitis B virus, Hepatitis C virus and *Treponema pallidum*. In addition, a donor specimen of viable, leukocyte-rich cells or tissue shall also be tested for Human T-lymphotropic Virus (HTLV) and CMV. Since leukocyte-rich nonviable lymphocytes may transmit latent HTLV and CMV, they too should be tested, and not exempted from the regulation

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Section 1271.85(e) requires donors of dura mater be assessed to detect evidence of transmissible spongiform encephalopathy (TSE). ASCP strongly agrees with this proposed requirement since the testing of dura mater for the presence of TSE may be the only avenue by which tissue-based products can be made safe.

Supplementary information in section II.E.3 of the document states that an autopsy should be performed by a "qualified neuropathologist." Many general pathologists who routinely provide neuropathology diagnostic services would not identify themselves as neuropathologists, yet they are qualified to perform this TSE assessment.

Section 1271.90(a)(2) allows a sexually intimate partner of the recipient to make a donation of reproductive cells or tissue without requiring testing. For clarification, does this section refer to semen, ova, and embryos? We note this inclusion in the introductory section of the proposed regulation, but believe specification is warranted in this section as well.

If you have questions or need additional information, please give me a call or contact Jennifer Burpee, MPH, ASCP Regulatory Associate, at (202) 347-4450.

Sincerely,

Stebbins Chandor, MD, FASCP
President

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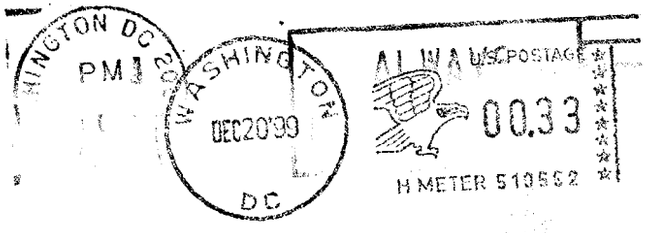

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